5;iManage;426308;1 @PFDesktop\::ODMA/MHODMA/HBS PATENT APPLICATION NSP/ACT/jjw DOCKET NO.: 0050.2060-001 FEB 2 7 2004 February 25, 2004 THE UNITED STATES PATENT AND TRADEMARK OFFICE ra T. Bortolin, Lalitha Parameswaran, James Harper, Johanna Bobrow, Mark A. Hollis, Drew Chapman Brown, Eric Scott Clasen and John Calvin Schmidt 10/616,904 Group Art Unit: 1634 plication 🕽 July 10, 2003 Examiner: Not Yet Assigned Confirmation No.: 1657 Title: APPARATUS AND METHOD FOR ISOLATING A NUCLEIC ACID FROM A **SAMPLE** CERTIFICATE OF MAILING OR TRANSMISSION I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on: Typed or printed name of person signing certificate **INFORMATION DISCLOSURE STATEMENT** Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Sir: This Information Disclosure Statement is submitted: or date of entry of the national ovisional application, including a

[ ]	under 37 CFR 1.129(a), or (First/Second submission after Final Rejection)
[X]	under 37 CFR 1.97(b), or (Within any one of the following time periods: three months of filing national application (other than a CPA) or stage in an international application; or before the mailing date of a first office action on the merits in a non-prov CPA, or a Request for Continued Examination).
[ ]	under 37 CFR 1.97(c) together with either:  [ ] a Statement under 37 CFR 1.97(e), as checked below, or
	[ ] a \$180.00 fee under 37 CFR 1.17(p), or (After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
[ ]	under 37 CFR 1.97(d) together with:
	[ ] a Statement under 37 CFR 1.97(e), as checked below, and
	[ ] a \$180.00 fee under 37 CFR 1.17(p), or (Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

[ ] under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Staten	ient Un	ier 3/ CFR 1.9/(e	2	
[ ]	any co	nmunication fron	n contained in this Information Disclosure Statement was first cited in a foreign patent office in a counterpart foreign application not more of the filing of this Information Disclosure Statement; or	
[]	No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.			ıed
Statem	nent Un	ler 37 CFR 1.704(	(Patent Term Adjustment) Applies to original applications (other than design) filed on or after May 29, 20	) ) )
[ ]	comm was no	inication from a for treceived by any	contained in the Information Disclosure Statement was cited in a preign patent office in a counterpart application and this communication individual designated in § 1.56(c) more than thirty days prior to the Disclosure Statement.	on
[ X ]	Enclos	ed herewith is for	m PTO-1449:	
	[X]	Copies of the cite	d references are enclosed.	
		[X] Since this and publis	application was filed after June 30, 2003, copies of issued U.S. patenshed U.S. applications are not required and are not being provided.	ts
	[ ]	Application No. [	d references are enclosed except those entered in prior application, U. ], to which priority under 35 U.S.C. 120 is claimed. [The earlies ins copies of the cited references.]	S. er
	[X]	The listed referent Report in a count	ces [AK, AC2, AD2] were cited in the enclosed International Search erpart foreign application.	
	[]	The "concise exp under 37 CFR 1.9	lanation" requirement (non-English references) for reference(s) [ 28(a)(3) is satisfied by:	]
		[ ] the explar	nation provided on the attached sheet.	
		[ ] the explan	nation provided in the Specification.	
			n of the enclosed International Search Report.	
		[ ] submissio and/or for	n of the enclosed English-language version of a foreign Search Reporeign Office Action.	t
		[ ] the enclos	ed English language abstract.	

[ ]	Appli	icant requests that the following n	on-published pending applic	cations be considered:
Examine: Initials	r's			
	_	U.S. Patent Application No. [	], by [inventor(s)], filed [	], Docket No.: [ ]
	_	U.S. Patent Application No. [	], by [inventor(s)], filed [	], Docket No.: [ ]
	_	U.S. Patent Application No. [	], by [inventor(s)], filed [	], Docket No.: [ ]
		Examiner	Date	_
	[ ]	A copy of each above-cited app	lication, including the curre	nt claims, is enclosed.
	[ ]	A copy of each above-cited app those entered in prior application 35 U.S.C. 120 is claimed.	lication, including the current on, U.S. Application No. [	nt claims, is enclosed, except ], to which priority under
The E	Examine ences we	er is requested to return a copy of ere considered with the next office	the above list of pending appe communication.	olications indicating which
It is r	equeste	d that the information disclosed he	erein be made of record in th	nis application.
Metho	od of pa	syment:		
[ ]	A che accon	ck for the fee noted above is encloped appropriate the fee noted above is encloped above is encloped. A copy of this S	osed, or the fee has been inc tatement is enclosed.	luded in the check with the
[ ]	Please	e charge Deposit Account 08-0380 sed.	0 in the amount of \$[ ]	. A copy of this Statement is
[X]	Please	e charge any deficiency in fees and	d credit any overpayment to	Deposit Account 08-0380.
		R	espectfully submitted,	
		Н	AMILTON, BROOK, SMIT	TH & REYNOLDS, P.C.
		В	Anabela Cristina Taylor Registration No.: 38,999 Telephone: (978) 341-0036 Facsimile: (978) 341-0136	Vaylor

Concord, MA 01742-9133 Dated: 1. 25, 2004 PTO-1449 REPRODUCED

INFORMATION DISCLOSURE OF IN AN APPROXIMATION February 25, 200

0050.2060-001 APPLICANTS

ATTORNEY DOCKET NO.

APPLICATION NO. 10/616,904

Laura T. Bortolin, et al.

FILING DATE July 10, 2003 CONFIRMATION NO. 1657

GROUP 1634

## (Use several sheets if necessary)

	U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	
	AA	5,234,809	08-10-1993	Boom et al.	
	AB	5,496,562	03-05-1996	Burgoyne	
	AC	5,660,984	08-26-1997	Davis et al.	
	AD	5,707,850	01-13-1998	Cole	
	AE	5,756,126	05-26-1998	Burgoyne	
	AF	5,807,527	09-15-1998	Burgoyne	
	AG	5,840,169	11-24-1998	Anderson	
	AH	5,863,801	01-26-1999	Southgate et al.	
	ΑI	5,927,386	10-26-1999	Burgoyne	
	AJ	5,939,259	08-17-1999	Harvey et al.	
	AK	5,976,572	11-02-1999	Burgoyne	
	AA2	5,985,327	11-16-1999	Burgoyne	
	AB2	6,037,465	03-14-2000	Hillebrand et al.	
	AC2	6,103,192 A	08-15-2000	Stapleton et al.	
	AD2	6,168,922	01-02-2001	Harvey et al.	
	AE2	6,218,176	04-17-2001	Berthold, et al.	
	AF2	6,264,814	07-24-2001	Lange	
	AG2	6,374,684	04-23-2002	Dority	
	AH2	6,428,962 B1	08-06-2002	Naegele	
	AI2	6,431,476	08-13-2002	Taylor et al.	
	AJ2	6,440,725	08-27-2002	Pourahmadi et al.	
	AK2	2002/0042125 A1	04-11-2002	Peterson et al.	
	AA3	2003/0129614 A1	07-10-2003	Parameswaran et al.	

EXAMINER	DATE CONSIDERED

1634

PTO-1449 REPRODUCED

## INFORMATION DISCLOSURE CITATION IN AN APPLICATION

February 25, 2004

(Use several sheets if necessary)

		Sheet 2 of 5
ATTORNEY DOCKET NO. 0050.2060-001	APPLICATION NO. 10/616,904	
APPLICANTS Laura T. Bortolin, <i>et al</i> .		
FILING DATE	CONFIRMATION NO.	GROUP

1657

FOREIGN PATENT DOCUMENTS				
	DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO
AL	WO 03/033740 A2	04-24-2003	Massachusetts Institute of Technology	
				1

July 10, 2003

EXAMINER	DATE CONSIDERED	

			5
PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 0050.2060-001	APPLICATION NO. 10/616,904	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	APPLICANTS Laura T. Bortolin, et al.		
February 25, 2004	FILING DATE	CONFIRMATION NO.	GROUP
(Use several sheets if necessary)	July 10, 2003	1657	1634

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
AR	Andreotti, P., "Portable Swab Sample Processor (SSP) and Analyzer for Rapid Detection of Biothreat Agents," Defense Advanced Research Projects Agency, Tissue Based Biosensors, Advanced Diagnostics, Activity Detection Technologies Principle Investigator Conference 2002, DARPA, Miami, Florida, February 18-21, 2002.
AS	"Cepheid Granted U.S. Patent Covering GeneXpert(R) Cartridge," at <a href="http://biz.yahoo.com">http://biz.yahoo.com</a> , June 5, 2002.
AT	Cepheid News; "Cepheid Collaborates on Major U.S. Postal Contract for Bio-threat Detection - Pilot Program to Employ GeneXpert® DNA-Detection System," at <a href="http://www.cepheid.com/pages/press/020513.html">http://www.cepheid.com/pages/press/020513.html</a> , Sunnyvale, CA, May 13, 2002.
AU	Cepheid Technology; "Fluidic Systems" at <a href="http://www.cepheid.com">http://www.cepheid.com</a> , June 5, 2002.
AV	"How GeneXpert Automates Sample Preparation," at <a href="http://media.corporate-ir.net">http://media.corporate-ir.net</a> , June 5, 2002.
AW	Levy, S., "A Fully Automated High-Throughput Nucleic Acid Purification System Using Silica Coated Magnetic Bead Technology," <i>Laboratory Robotics Interest Group, New England Chapter, Poster Session, March 26, 2002</i> , from http://www.lab-robotics.org/New_England/Posters/LRIG-New%20England%20Posters%20March%2026,2002.pdf.
AX	Parameswaran, L., "Development of Recovery Techniques for Organisms and Nucleic Acids from Complex Samples", <i>Third Annual Biodetection Technologies 2003 International Symposium</i> , from <a href="http://www.knowledgepress.com/event/12111105.htm">http://www.knowledgepress.com/event/12111105.htm</a> .
AY	Schmidt, J.C., "A Portable Biodetection System Incorporating Semi-Automated Sample Preparation," Detection Technologies - The Next Generation in Identification and Analysis, Arlington, Virginia, December 5-6, 2002, <a href="http://www.knowledgepress.com/events/7191716.htm">http://www.knowledgepress.com/events/7191716.htm</a> .
AZ	Taylor, Michael T., et al., "Lysing Baterial Spores by Sonication through a Flexible Interface in a Microfluidic System," Anal. Chem., 73:492-496(2001).
AR2	Tu, Shu-I, et al., "Applications of Time-Resolved Fluoroimmunoassay to Detect Magnetic Bead Captured Escherichia Coli 0157:H7," Journal of Rapid Methods and Automation in Microbiology, 9:71-84 (2001).
AS2	Xtrana: Products: Nucleic Acid Testing; "SCIP: Self Contained Integrated Particle," <a href="http://www.xtrana.com">http://www.xtrana.com</a> , June 5, 2002.

ſ	EXAMINER	DATE CONSIDERED
Į		